American Chemistry Council Good Chemistry Makes It Possible

VCCEP Workshop
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Perspectives on Tiered Exposure Assessments for VCCEP

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VCCEP Exposure Assessment

There is no single method or "cookbook" for developing exposure assessments applicable to all substances and all circumstances.

VCCEP Exposure Assessment

Some or all of the components discussed in our document may or may not be relevant for a specific case.

VCCEP Exposure Assessment

The assessment must support a scientifically sound and satisfactory risk-based characterization for a given chemical for a given tier.

VCCEP Exposure Assessment

Critical components of an exposure assessment, at any tier, are:

- scientific quality,
- completeness
- transparency

ACC supports inclusion of exposure at each evaluation tier:

- to place the hazard data in context
- to help in determining
  - whether children are protected from potential risks with acceptable degree of scientific confidence
  - whether additional data are needed

Focus on children

- *age dependent activities influence exposures*
- *in utero* events important to consider
  - extend exposure assessments to the embryonic and fetal period when developmental and/or reproductive effects are identified

Quantifying Exposures

- Biomonitoring data - only one part of exposure assessment
- Modeling may be needed and is acceptable
  - Conservative screening methods are acceptable
- If adequate data is available – should be used

Conceptual Alignment with EPA

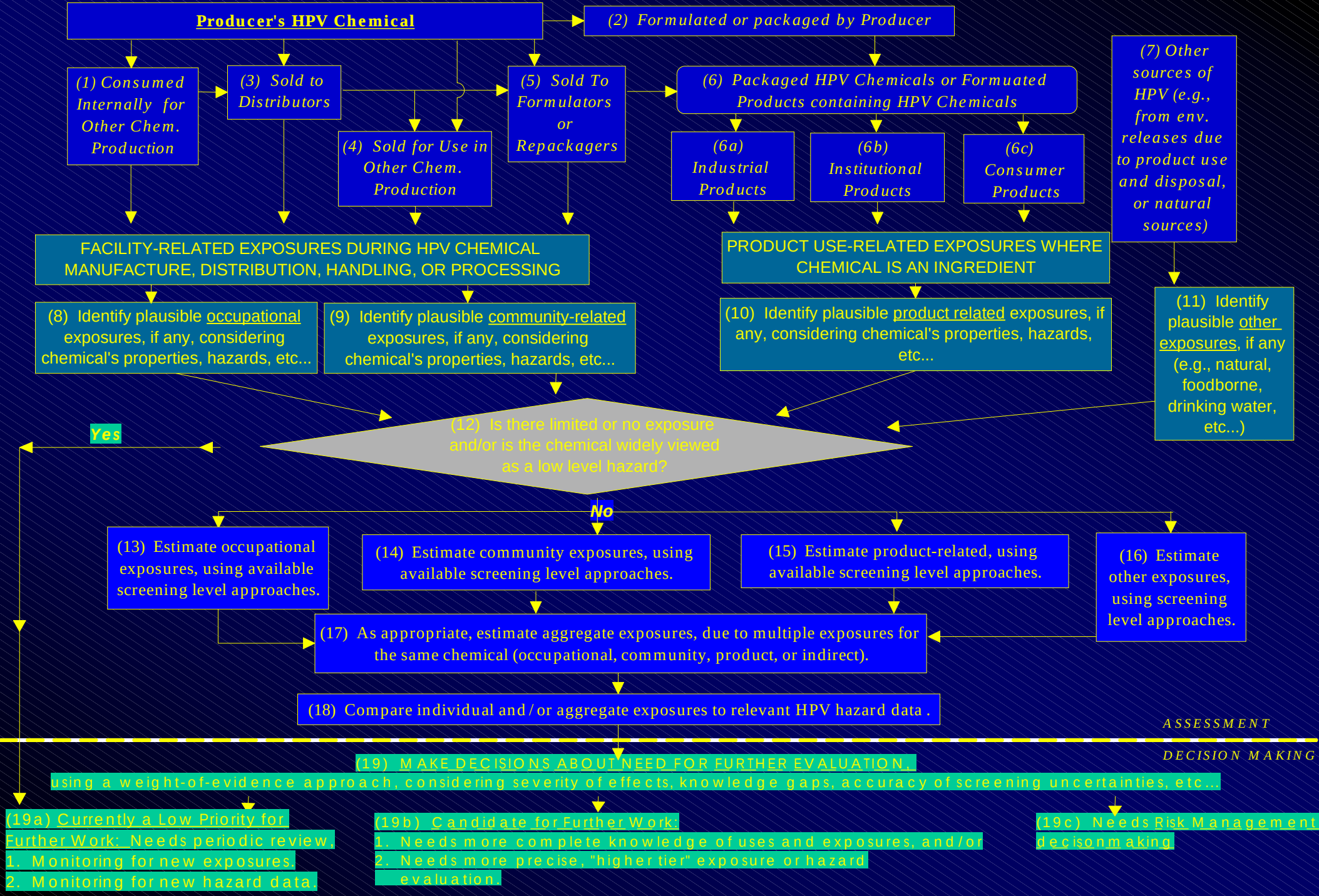
OPPT http://www.epa.gov/opptintr/exposure/):

"Screening-level assessments that allow one to quickly prioritize exposures for further work; these assessments are based primarily on readily available data, conservative assumptions and simple models.

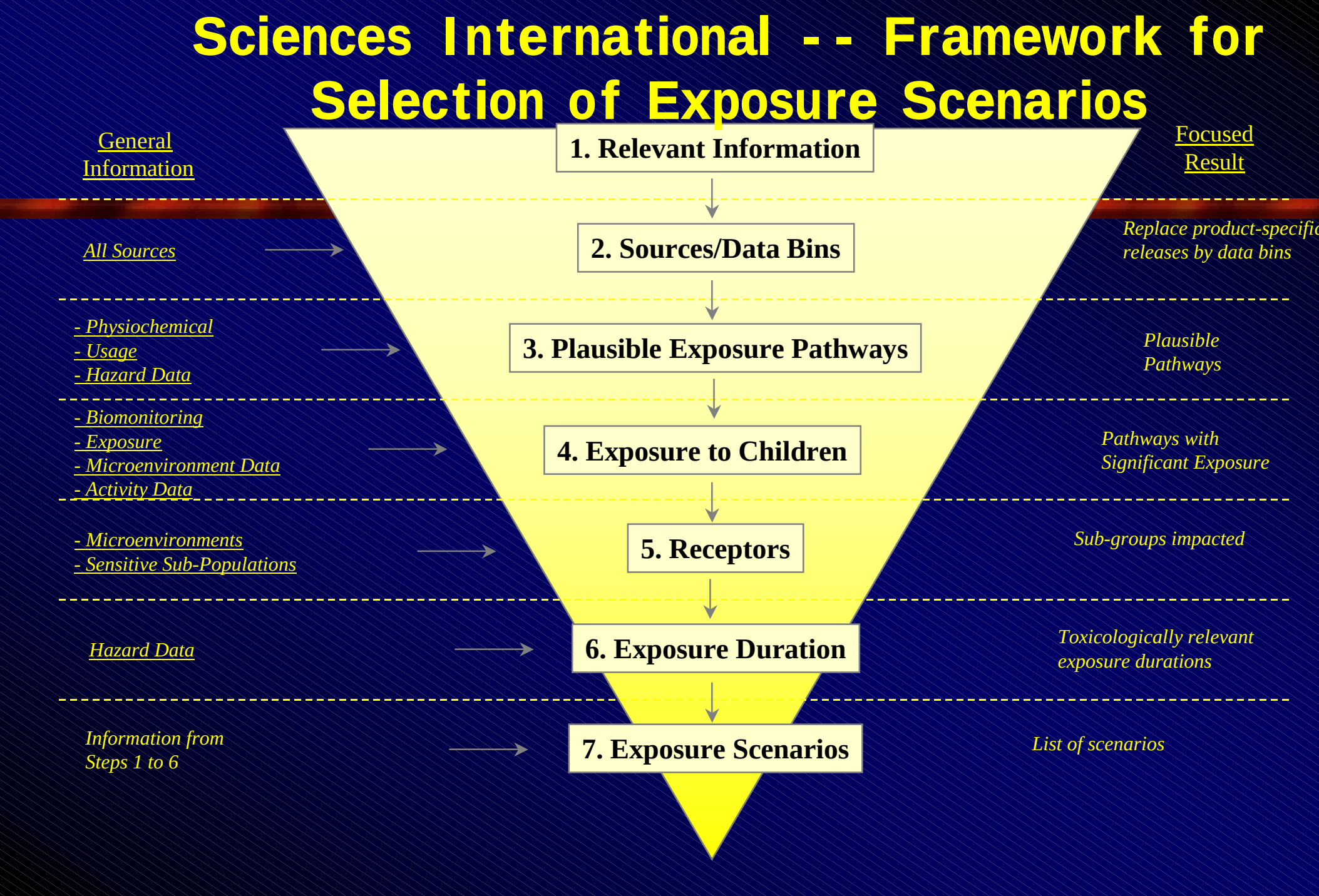
"Advanced assessments which focus on higher priority exposures that attempt to represent actual environmental conditions and exposures; these assessments require more data and make use of more sophisticated models or ideally, a well-designed monitoring study."

Conceptual Construct for Exposure Assessment

- Alliance for Chemical Awareness (see handout)
- Sciences International – conceptual framework as illustrated by a case study of a hypothetical substance


Producer's HPV Chemical
(2) Formulated or packaged by Producer
(1) Consumed Internally for Other Chem. Production
(3) Sold to Distributors
(4) Sold for Use in Other Chem. Production
(5) Sold To Formulators or Repackagers
(6) Packaged HPV Chemicals or Formuated Products containing HPV Chemicals
(6a) Industrial Products
(6b) Institutional Products
(6c) Consumer Products
(7) Other sources of HPV (e.g., from env. releases due to product use and disposal, or natural sources)
FACILITY-RELATED EXPOSURES DURING HPV CHEMICAL MANUFACTURE, DISTRIBUTION, HANDLING, OR PROCESSING
PRODUCT USE-RELATED EXPOSURES WHERE CHEMICAL IS AN INGREDIENT
(8) Identify plausible occupational exposures, if any, considering chemical's properties, hazards, etc...
(9) Identify plausible community-related exposures, if any, considering chemical's properties, hazards, etc...
(10) Identify plausible product related exposures, if any, considering chemical's properties, hazards, etc...
(11) Identify plausible other exposures, if any (e.g., natural, foodborne, drinking water, etc...)
(12) Is there limited or no exposure and/or is the chemical widely viewed as a low level hazard?
Yes
No
(13) Estimate occupational exposures, using available screening level approaches.
(14) Estimate community exposures, using available screening level approaches.
(15) Estimate product-related, using available screening level approaches.
(16) Estimate other exposures, using screening level approaches.
(17) As appropriate, estimate aggregate exposures, due to multiple exposures for the same chemical (occupational, community, product, or indirect).
(18) Compare individual and/or aggregate exposures to relevant HPV hazard data .
ASSESSMENT
DECISION MAKING
(19) MAKE DECISIONS ABOUT NEED FOR FURTHER EVALUATION, using a weight-of-evidence approach, considering severity of effects, knowledge gaps, accuracy of screening uncertainties, etc...
(19a) Currently a Low Priority for Further Work: Needs periodic review,
1. Monitoring for new exposures.
2. Monitoring for new hazard data.
(19b) Candidate for Further Work:
1. Needs more complete knowledge of uses and exposures, and/or
2. Needs more precise, "higher tier" exposure or hazard evaluation.
(19c) Needs Risk Management decisonmaking

Sciences International -- Framework for Selection of Exposure Scenarios



Each assessment will be unique

A *'fill in the blanks'* or a *'check list'* approach is inappropriate

- Use & Exposure Information Program approach (UEIP) overemphasizes industrial exposures
- Inflexible
- Doesn't effectively focus resources on children's exposures

Tier 1 -- Screening Level Exposure Assessment

- Begin with SIAR type approach; identify production volumes, major use functions/categories, potential sources of release to the environment, and physical form of the marketed product
- Obtain other readily available exposure data (e.g. monitoring data)
- Identify potential pathways and routes of children's exposures
- Develop qualitative and semi-quantitative estimation of intakes based on conservative default assumptions
  Two steps:
  - Assess chemical concentration in medium
  - Estimate intake from child's contact with medium
- Set aside chemicals and specific pathways where intake(s)/dose(s) of toxicological concern is/are unlikely

Tier 2 -- Refined Exposure Assessment

- Refine critical source/pathway info
- If applicable, assess adult exposures based on reproductive/ /developmental data
- Modify defaults with more realistic, scenario-specific data
- Incorporate variability and uncertainty in assessment
- Focus on most relevant & sensitive uses that dominate conservative exposure estimates

Tier 3 -- Detailed Exposure Assessment

- In depth studies of critical sources or pathways
- Evaluate detailed exposure related behaviors—habits and practices
- Use better models of inter- and intra- individual variation
- Use better data on temporal, spatial variation of source terms and exposure point concentrations
- Combined monitoring and modeling approaches
- Use monitoring data to confirm model predictions
- Use modeling to extend/verify monitoring predictions

VCCEP – A Risk Based Evaluation Process

- The tiered evaluation process in the VCCEP pilot:
  - integrates data on the nature and magnitude of toxicity with information on the frequency, duration and level of exposure.
  - Promotes risk-based decision making

VCCEP – A Risk Based Evaluation Process

The risk-based evaluation determines what, if any additional:

specific toxicity tests

and/or

exposure appraisals

are appropriate for specific substances to suitably characterize potential risks to children with an acceptable degree of scientific confidence.

Critical Features of an Exposure Assessment

- scientific quality
- completeness
- transparency
  - documentation
  - clarity